

# Tab A-6

NATIONAL ASSOCIATION OF MEDICAID FRAUD CONTROL UNITS

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Alaska Pharmacy Director  
State Medicaid Agency  
4501 Business Park Blvd.  
Suite 24  
Anchorage, Alaska 99503

Dear Medicaid Pharmacy Director:

The joint State and federal investigation of drug price misrepresentation by pharmaceutical manufacturers has resulted in the first concluded settlement with a manufacturer, Bayer, Inc. Under the terms of this settlement, Bayer will repay a total of \$14 million to cover excess Medicaid payments made for its products, and will enter into a Corporate Integrity Agreement with the Office of the Inspector General of the U. S. Department of Health and Human Services, to ensure the future accuracy and integrity of drug price communications.

Most importantly, from your perspective, the agreement reached requires Bayer to submit to all Medicaid Pharmacy Directors\* whose states have entered into the settlement, along with First DataBank and HCFA OIG, quarterly certified statements identifying the actual average sale prices of its products, weighted to reflect the volume of sales at each price. Indeed, it is our

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\* The average sale price information will be sent to the same address as this letter. If you wish to designate another address, please notify your State MFCU of your desire to do so.

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intention to make the communication of certified pricing data a mandatory component of any subsequent resolutions of our drug pricing investigation with pharmaceutical manufacturers. This unprecedented access to true market prices will provide you an extraordinary opportunity to compare providers' real acquisition costs with Medicaid reimbursement prices and, we believe, provide you the basis for determining where and how Medicaid prices should be adjusted.

Obviously, while this data has enormous potential value, its true benefits can only be achieved through the efforts of State pharmacy directors to make use of it. *We emphasize that each State will be obliged to determine how this data can be accommodated into its existing pricing formula. Unless and until states take such efforts, and provide First DataBank with specific instructions as to how the data is to be used, this pricing information will have no effect.* Consequently, we write to inform you at the earliest stage possible of the nature and import of the pricing data you will be receiving soon from Bayer and subsequently from other manufacturers.

#### The New Price Information You Will Receive

First, we wish to clearly communicate to you what the numbers you will be receiving represent. As set forth in the settlement, manufacturers will be submitting to each state:

"...the average of all final sale prices charged by [the manufacturer] for the drug or biological product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate Program purposes, pursuant to 42 USC § 1396r-8, and direct sales to hospitals...net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates and all other price concessions provided by [the manufacturer]...that result in a reduction of the ultimate cost to the purchaser."

Thus, "average sale price" should be understood to mean exactly what it says; it is neither an Average Wholesale Price, nor a Wholesale Acquisition Cost, but the *average* of all prices charged to the overwhelming majority of customers. This average sale price will, moreover, be weighted to reflect the volume of sales at each price, i.e., ten sales at \$1.00 and one sale at \$0.50 will produce, not a flat average of \$0.75, but a weighted average sales price of \$0.95.

Additionally, under the terms of the settlement, Bayer will refrain from submitting AWP information for purposes of setting Medicaid reimbursement for the following drugs:

- Koate-HP Antihemophilic Factor (Human)
- Kogenate Antihemophilic Factor (Recombinant)
- Konyne-80 Factor IX Complex (Human)
- Gamimune N, 5% Immune Globulin Intravenous (Human, 5%),
- Gamimune N, 10% Immune Globulin Intravenous (Human, 10%),
- Thrombate III Antithrombin III (Human).

First DataBank will consequently ascertain and communicate a Medicaid AWP for these products independently of any information from Bayer. Bayer will continue to submit AWP's for other drugs it manufactures, but we reemphasize that the average sale price information Bayer will provide to State Medicaid programs will encompass *all* of its products.

#### Use of the Average Sale Price Data

A drug's average sale price will consequently afford you a reliable standard for determining what the true market price of a drug is, at least on an average basis. How this information may ultimately be used and what relationship this market price will or should bear to final reimbursement prices are, of course, questions properly left to you and other Program personnel. The Medicaid Fraud Control Units involved in this investigation have pursued the limited goals of halting the communication of false information, and ensuring that Medicaid Program staff have reliable information on which to make decisions. Once those goals have been achieved, the determination as to what levels of reimbursement ought to be, relative to a drug's average sale price, is appropriately left for consideration by Pharmacy Directors, Medicaid Program Directors and other policy makers. *Again, absent your direction to First DataBank, or any subsequent price reporting agency, as to how your state wishes use average sale price information, this data will have no impact on Medicaid prices and you will continue to be susceptible to any price misrepresentations by manufacturers.*

#### The Impact on Bayer

Another matter we wish to address concerns Bayer, the initial manufacturer to reach a resolution of its AWP liability. As such, Bayer will be, at least for a time, the only manufacturer to provide you with certified average sale price information, and how that information is used may have a profound effect on our continuing investigation. Our inquiry has indicated that Medicaid providers who bill for pharmaceuticals maximize their reimbursement by migrating to drugs with a high "spread" between AWP and purchase price, and away from lower spread drugs. Consequently, the existing market exhibits the perverse effect of "punishing" the truthful reporter of price data, whose lower reimbursement cannot compete with the larger spread generated by dishonest competitors. Were the Bayer price data to be used to cause this same result – lowering the market appeal of its products relative to its competitors – the effect would be doubly perverse: truthful price reporting by the first company to reach a settlement with the Medicaid Fraud Control Units would operate only to its economic disadvantage. It could hardly be expected that, if this were the outcome, any other manufacturer would consider either providing accurate price data or entering into a settlement with the government.

Of course, we stress, this is not to suggest that the Bayer information not be used. On the contrary, we would *urge* that it be used, effectively and productively, but in a way that provides no competitive advantage to other manufacturers less cooperative and less truthful than Bayer is. Again, the means by which this might be accomplished, *e.g.*, by using Bayer data as a basis for setting State maximum prices, are subjects better left to your discretion.

As we indicated previously, we expect that our continuing investigation will result in more such negotiated resolutions with other pharmaceutical manufacturers in the future. It is our

intention that the provision of accurate information, enforced by the prospect of severe penalties for false submissions in every state, will enable Program reimbursements to be determined far more fairly and rationally than they are at present. We hope that you perceive the potential of this certified pricing data with an equally positive perspective.

Thank you for your continued cooperation and consideration in this matter.

Very truly yours,

For the NAMFCU Drug Pricing Team:

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cc: State MFCU Directors